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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,985	07/15/2003	Thomas David Starkey	N9464-ICW	3040
23456	7590	08/26/2004		
WADDEY & PATTERSON			EXAMINER	
414 UNION STREET, SUITE 2020				SNOW, BRUCE EDWARD
BANK OF AMERICA PLAZA			ART UNIT	PAPER NUMBER
NASHVILLE, TN 37219				3738

DATE MAILED: 08/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/619,985	STARKEY, THOMAS DAVID	
	<b>Examiner</b>	<b>Art Unit</b>	
	Bruce E Snow	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on \_\_\_\_\_.  
2a)  This action is **FINAL**.                            2b)  This action is non-final.  
3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 1-34 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5)  Claim(s) \_\_\_\_\_ is/are allowed.  
6)  Claim(s) \_\_\_\_\_ is/are rejected.  
7)  Claim(s) \_\_\_\_\_ is/are objected to.  
8)  Claim(s) 1-34 are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892) 4)  Interview Summary (PTO-413)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date. \_\_\_\_ .  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_ .  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_ .

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, 8-11, 14-16, 18-22, 24-26, 29-34, drawn to a diastolic volume limiting device (DIVOLA), classified in class 623, subclass 3.1.
- II. Claims 27-28, drawn to a volume compensation device (VCD), classified in class 600, subclass 18.
- III. Claims 6-7, 12-13, 17, 23 are drawn to a combination of group I (DIVOLA) and group II (VCD), classified in class 623, subclass 3.16.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention II (VCD) has separate utility of being implanted in a heart chamber by itself and passively or actively (inflating) assisting in pumping blood. The device could also be used as a skin expander. See MPEP § 806.05(d).

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination (i.e. claim 12) as claimed does not require the particulars of the subcombination (i.e. claim 1) as claimed not requiring a

plastic sac with openings. The subcombination has separate utility as being used by itself to line a heart chamber exactly fitting said chamber to limit expansion thereof. The device could also be inflated and used as a mold to shape a heart chamber in a surgical procedure.

Inventions I and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination (i.e. claim 12) as claimed does not require the particulars of the subcombination (i.e. claim 27) as claimed not spacing being adjustable or the wall being connected. The subcombination has separate utility of being implanted in a heart chamber by itself and passively or actively (inflating) assisting in pumping blood. The device could also be used as a skin expander.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

A telephone call was made to Mr. Waddly to request an oral election to the above restriction requirement, but did not result in an election being made.

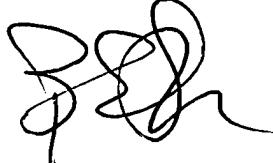
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (703) 308-3255. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (703)308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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BRUCE SNOW  
PRIMARY EXAMINER